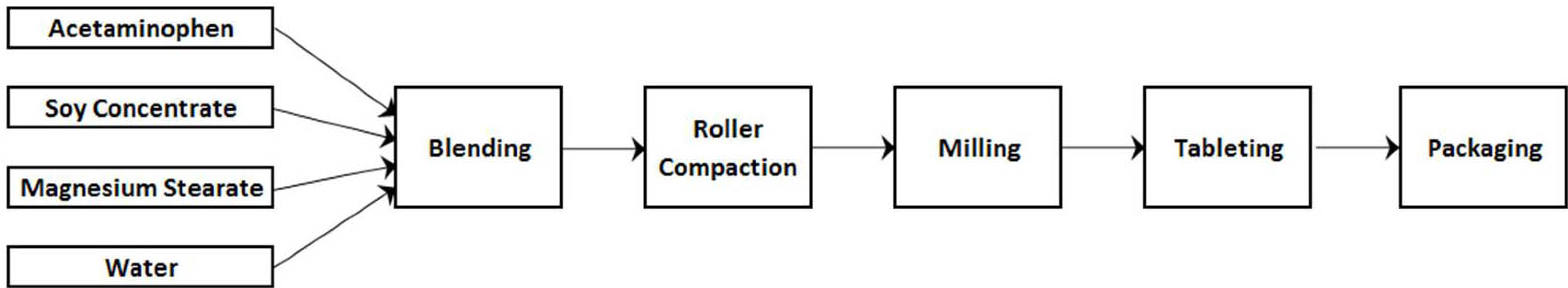


Manufacturing Process Flowchart



1 – BLENDING

- Active pharmaceutical ingredient and excipients combines
- Produces a homogenous mixture



2 – ROLLER COMPACTION

- Uses force to bind particles
- Dry compression granulation
- No drying step needed
 - Saves time and energy costs
- Creates ability to have a continuous process



3 – MILLING

- Creates granules of uniform sizes
- Improves flowability characteristics of initial powder blend



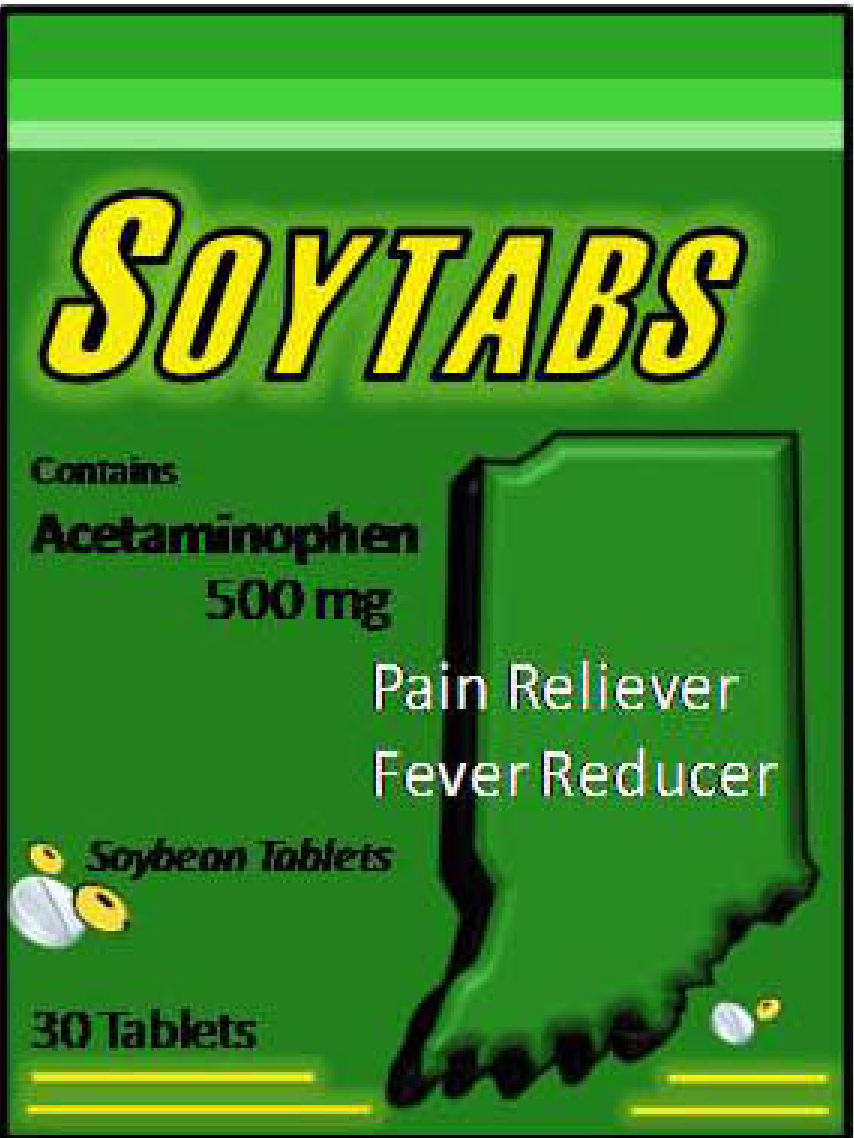
4 – TABLETING

- Compression of granules into tablets
- Single station tablet press – Formulation
- 16 station tablet press – Production



5 – PACKAGING

- Logo and package design resemble similar products
- White, opaque bottles
- Child resistant caps with seal
- White gift boxes with gloss finish
- Cotton in bottle
 - Shipping cushion
- Desiccant in bottle
 - Moisture absorber



Please Read Product Label

<p>Active ingredient Acetaminophen 500 mg</p> <p>Uses Temporarily relieves minor aches and pains due to: • Headache • Muscular aches • Neuralgia • Rheumatism</p> <p>Warnings Do not use this product if taking another medication containing acetaminophen. Abuse warning: Abuse of acetaminophen may cause damage to the liver. Please speak with your doctor before taking acetaminophen or other medications for pain if your daily alcohol intake is 8 or more drinks. Allegiant warning: This product contains soy. Ask your doctor if this product is right for you. Overdose warning: Taking more than the recommended dose can cause liver damage and serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms. Keep use and ask doctor if: • Pain gets worse or lasts more than 10 days • New symptoms occur • Rash or hives develop • Fever gets worse or lasts for more than 3 days If pregnant or breastfeeding, ask a health professional before use. Keep out of reach of children.</p> <p style="text-align: center; font-weight: bold;">Do not use with other products containing Acetaminophen</p>		<p>Directions • Do not use more than directed (see overdose warning)</p> <p>adults and children 12 years and over • Take 2 tablets every 4 to 6 hours while symptoms last. • Frequent tablets may be used but should be taken irregularly. Do not exceed 8 tablets in 24 hours.</p> <p>children under 12 years • do not use this adult product in children under 12 years of age. This will provide more than the recommended dose (overdose) and could cause liver damage.</p> <p>Inactive ingredients soy protein concentrate, magnesium stearate</p> <p>Other information • Store between 20-25°C (68-77°F) • do not use if carton is opened or neck wrap or inner seal is broken or missing. • This unit complies with FDA, Health, and Regulatory rules. Questions or comments? call SoyTABS at 1-800-655-6555</p> <p style="text-align: right;">Distributed by: Soy Team #36 EXP: 2013 Lot No: 0098816321</p>
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SOYTABS

A Pharmaceutical Tablet Using Soy Concentrate as an Excipient

Danielle Carpenter, Krista Eakins - BFPE

SOYTABS

- Pharmaceutical tablets
- Soy Concentrate used as a binder
- Roller Compaction used as a dry granulation step
- High drug-loading of Acetaminophen (70%)

PRODUCT FORMULATION

Ingredients	Amount Added
Soybean Protein Concentrate	300 grams (30%)
Acetaminophen	700 grams (70%)
Magnesium Stearate	5 grams (0.5% of a 1000 batch)
Water	70 grams (7% of a 1000 g batch)

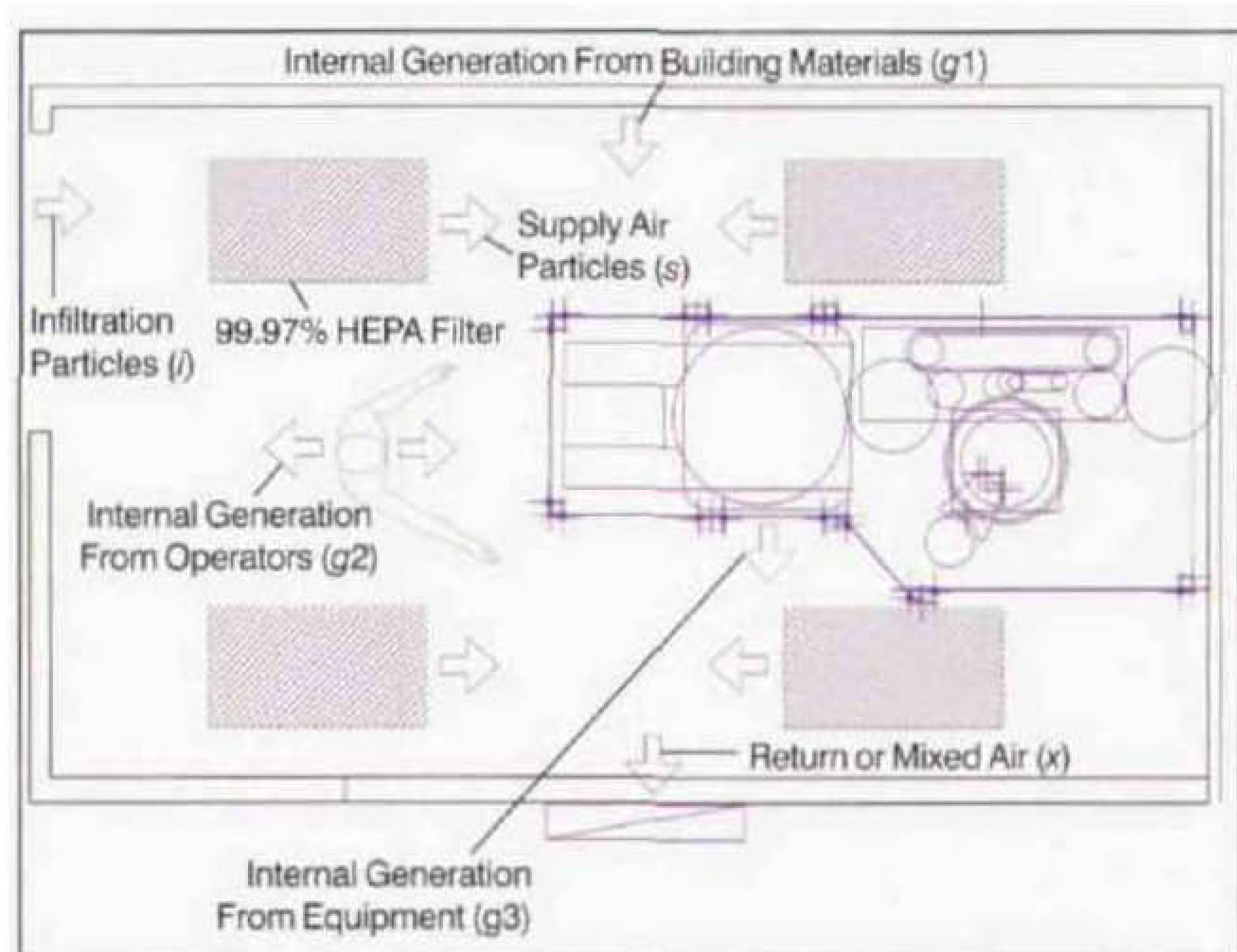
PROBLEM

- Wet granulation increases energy costs and time due to drying step

BENEFITS

- Roller Compaction replaces Wet Granulation + Drying
 - Saves time and energy costs
 - In combination with high drug-loading
- Soy Concentrate replaces current binders
 - Lower material cost
 - Introduces a new potential excipient for new drug molecules coming to market
- The byproducts of soy concentrate extraction can be processed within Indiana

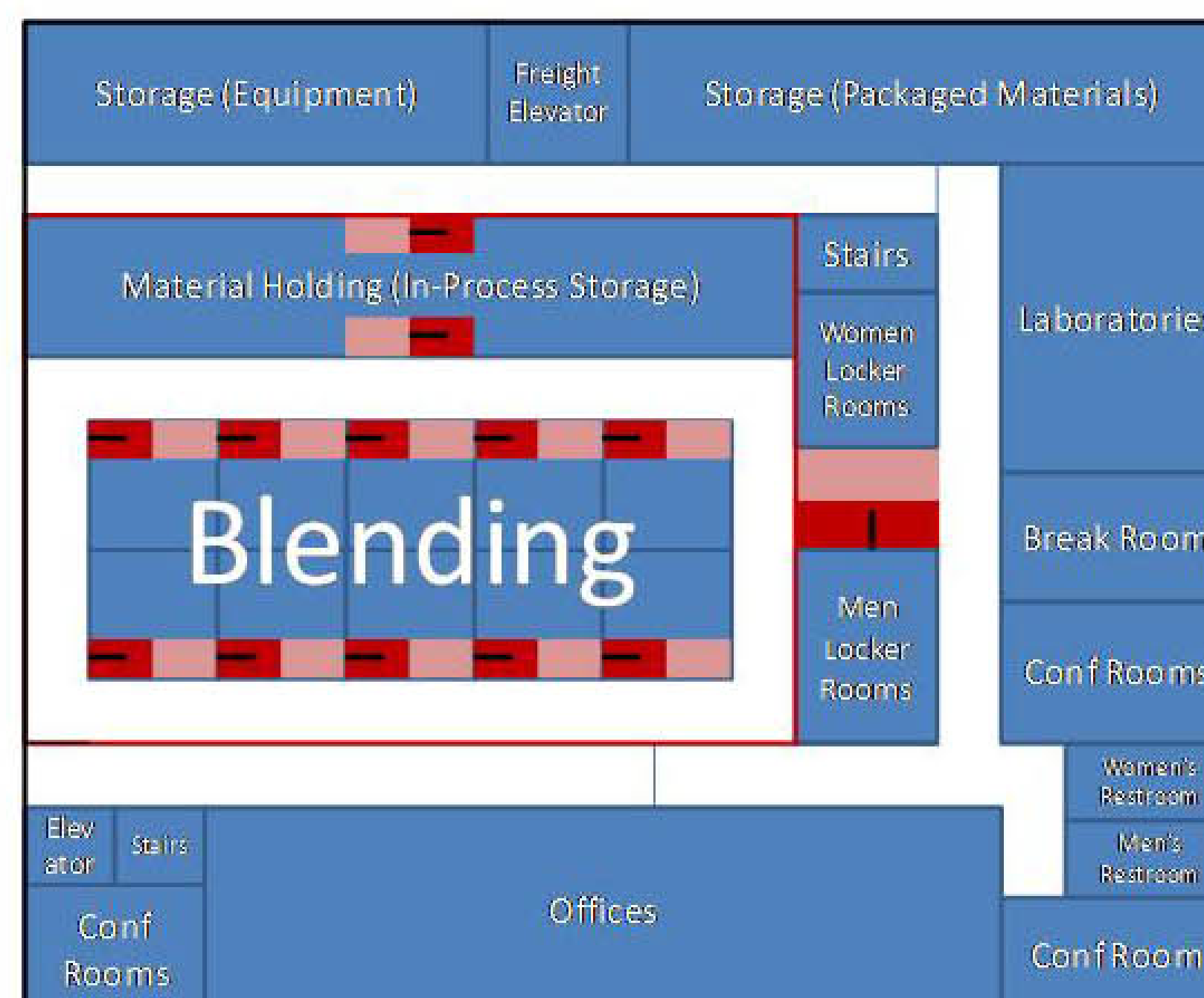
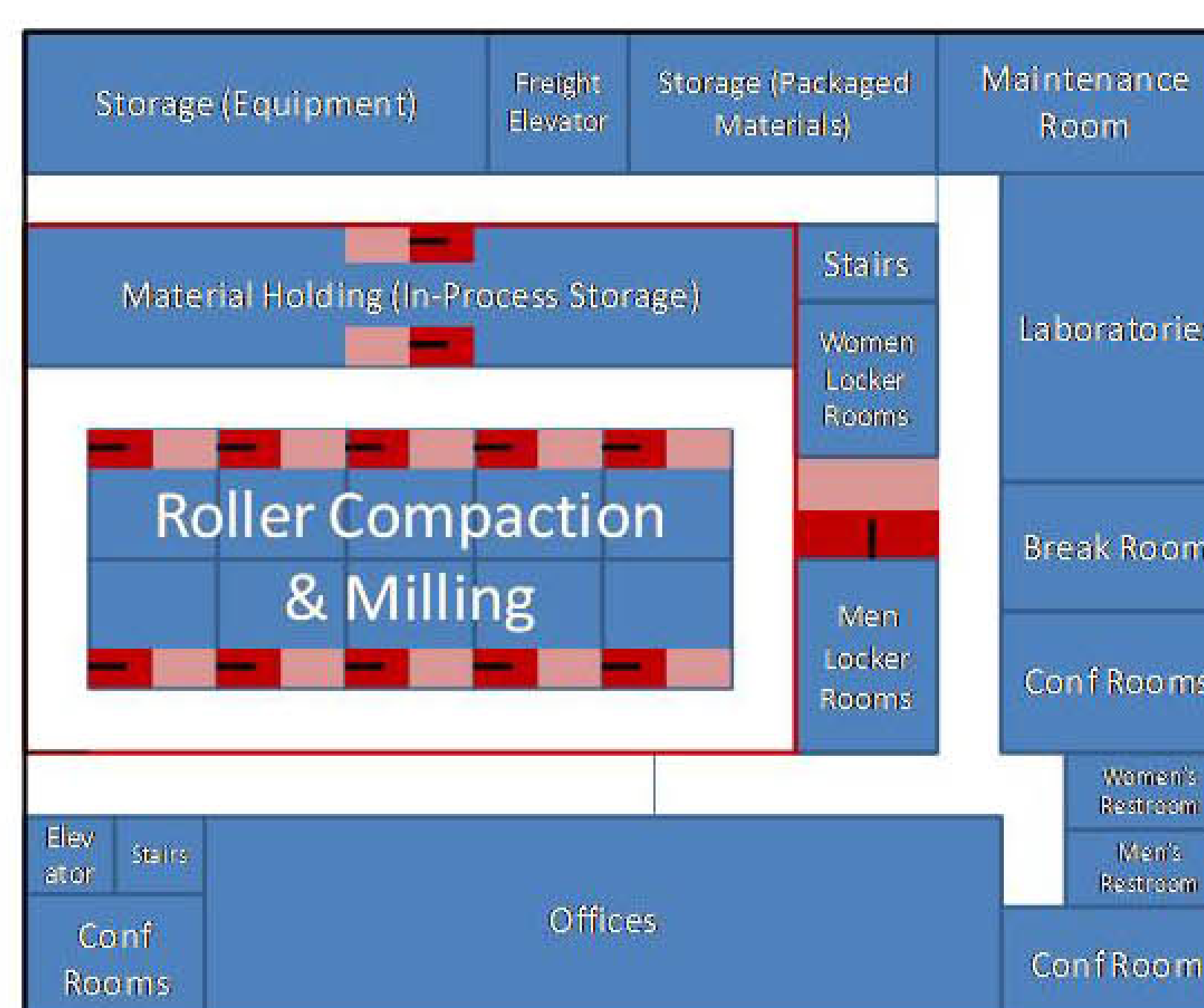
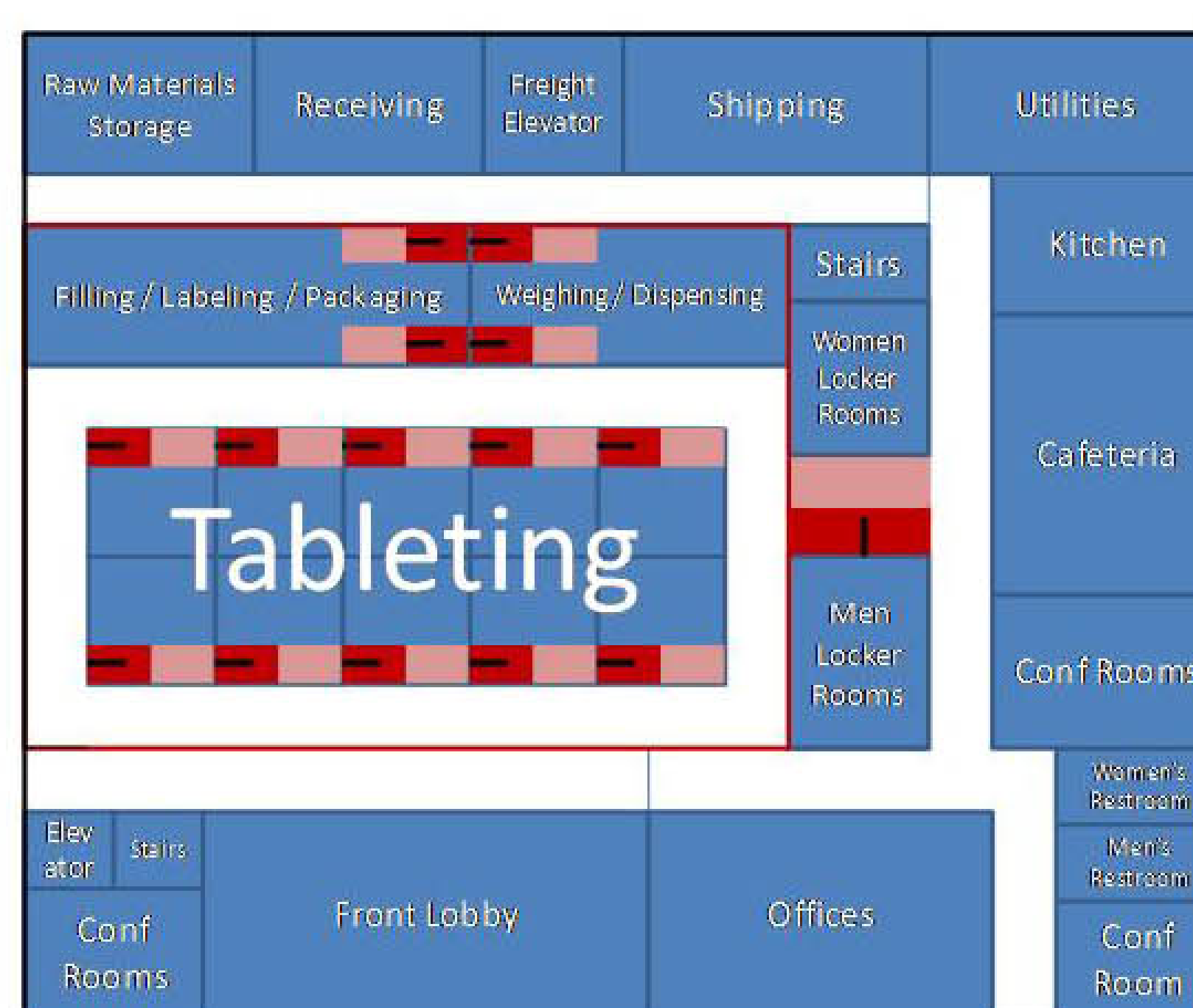
Clean Room Design



Three sources of airborne particles:

- Internal generation
- Supply air
- Infiltration from adjacent spaces

Plant Layout Floors 1 - 3



ISO 14644 & Federal Standard 209E

Class	maximum particles/m ³						FED STD 209E equivalent
	≥0.1 μm	≥0.2 μm	≥0.3 μm	≥0.5 μm	≥1 μm	≥5 μm	
ISO 1	10	2					
ISO 2	100	24	10	4			
ISO 3	1,000	237	102	35	8		Class 1
ISO 4	10,000	2,370	1,020	352	83		Class 10
ISO 5	100,000	23,700	10,200	3,520	832	29	Class 100
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293	Class 1000
ISO 7				352,000	83,200	2,930	Class 10,000
ISO 8				3,520,000	832,000	29,300	Class 100,000
ISO 9				35,200,000	8,320,000	293,000	Room air

Economic Analysis

THE MARKET

- In 2007, the market size for the US for binders and fillers was \$650 million
- Worldwide, the binder and filler market was \$1.0 billion in 2007

MARKET SIZE AND GROWTH

- The market size for binders and fillers in the US is projected to increase to \$854.8 million by 2012
- The Worldwide binder and filler market is projected to increase to over \$1.3 billion by 2012

STRENGTHS

- Our soy excipient is a natural product
- Utilizes simplified processing method
- Simple formulation
- Allows for high drug load formulations
- Compatible with roller compaction
- Less exposure

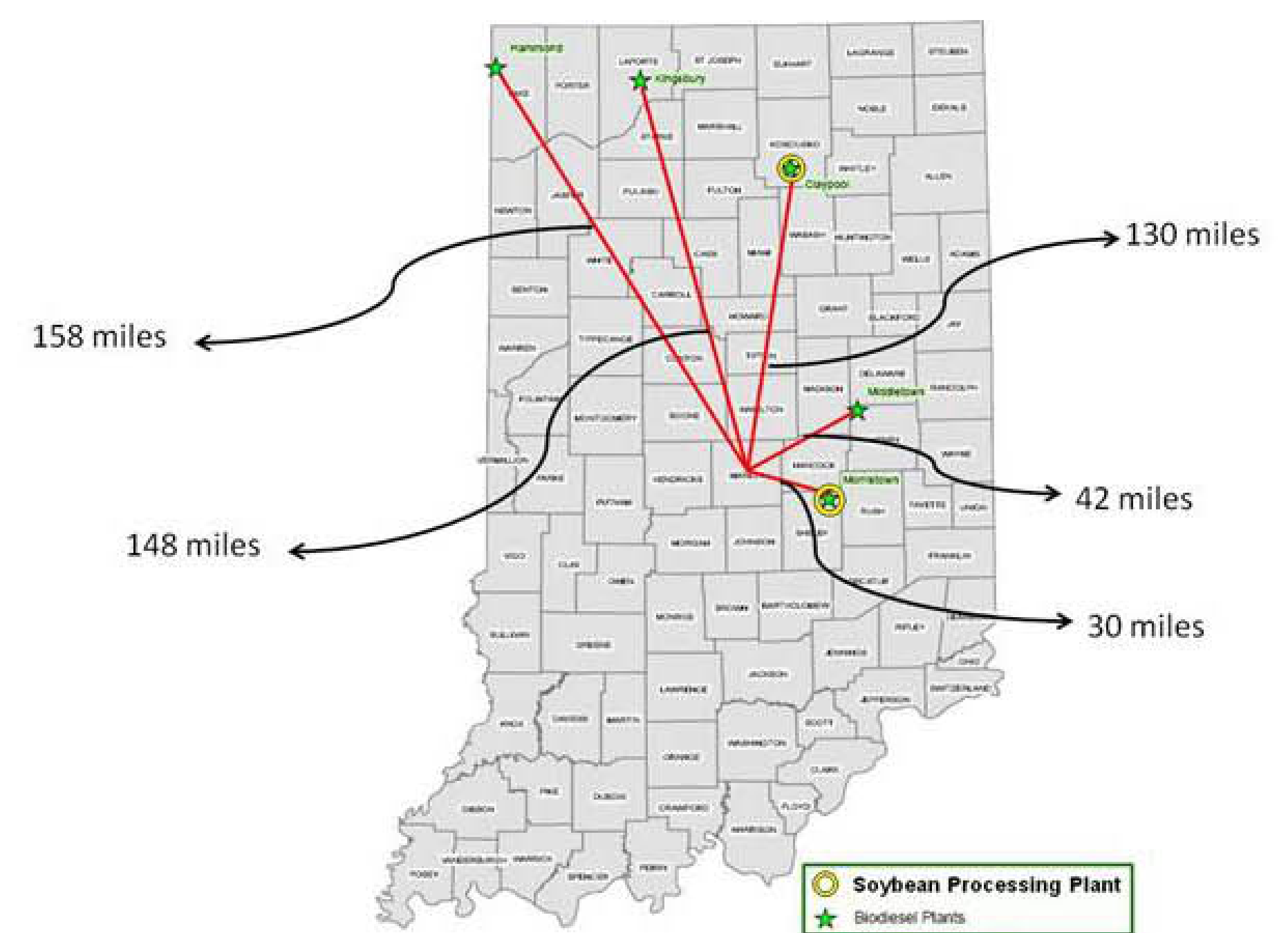
COMPETITION

- Other excipient manufacturers include Roquette, Rosswell Inc., and FMC BioPolymer
- Other excipients which function as binders that would compete with our excipient are Microcrystalline Cellulose, Starch, Lactose, and many more

Equipment Comparison – Energy Consumption per month

	Blender	Roller Compactor/ Mill	Tablet Compressor	Wet Granulation with Drying
Power Consumption [kW]	16	23.2	13	41
Power Consumption [HP]	21.76	31.55	17.68	55.76
Batch Time per step [hr]	0.25	0.5	3.46	3.00
kJ / Batch	14,400.00	41,760.00	162,028.99	442,800.00
kJ / Campaign	144,000.00	417,600.00	1,620,289.86	4,428,000.00
Campaigns / month	50.0	50.0	50.0	50.0
kJ / month	7,200,000.0	20,880,000.0	81,014,492.8	221,400,000.0
BTU/month	6,824,283.3	19,790,421.5	76,786,923.4	209,846,711.0

** Making the assumption that a batch is 53 kg, there are 10 batches in 1 campaign, and 50 campaigns per month



Locations of soybean processing plants and biodiesel plants in relation to a pharmaceutical company

If all binders and fillers were replaced with Soy Concentrate

Year	Location	Material	Required Tons of Material	Required Bushels of Soybeans
2007	United States	Binders and Fillers	130 Million	13 Billion
2007	Worldwide	Binders and Fillers	210 Million	21 Billion
2012	United States	Binders and Fillers	178 Million	17.8 Billion
2012	Worldwide	Binders and Fillers	282 Million	28.2 Billion

1% Penetration into binder and filler market

One Percent Market Penetration					
Year	Location	Material	Required Tons of Material	Required Bushels of Soybeans	Soybeans sold (\$) *
2007	United States	Binders and Fillers	1.3 Million	130 Million	1.21 Billion
2007	Worldwide	Binders and Fillers	2.1 Million	210 Million	1.95 Billion
2012	United States	Binders and Fillers	1.78 Million	178 Million	1.65 Billion
2012	Worldwide	Binders and Fillers	2.82 Million	282 Million	2.62 Billion

* Calculated at current market price of \$9.30/bu



THANK YOU'S

- Indiana Soybean Alliance
- Jennifer Nordland
- Dr. Martin Okos
- Dr. Bernie Tao
- Dr. Hank Feeser
- Solae ®
- Ryan McCann
- Walgreens
- Elizabeth Topp